DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

January 7, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-27

John H. Wriglesworth, President
X-CEL Feeds, Inc.
5436 South Washington Street
Tacoma, Washington 98409

WARNING LETTER

Dear Mr. Wriglesworth:

During an FDA inspection of your feed mill on April 12, 1999, a sample of "X-CEL TURKEY STARTER - FINISHER MEDICATED CRUMBLES," product #601, was collected. This feed contains the active ingredients amprolium and ethopabate. The Type A medicated article, amprolium and ethopabate, is not approved for use in turkeys. The turkey feed is therefore in violation of Section 501(a)(6) and Section 512 of the Food, Drug and Cosmetic Act (the Act).

Your label for product #601 states that the product is a turkey starter-finisher feed and additionally has a prominently displayed icon of a turkey. The use of this drug combination, amprolium and ethopabate, is currently approved only in chicken feed as specified in the Code of Federal Regulations, Title 21, Part 558.58 (21 CFR 558.58).

The above is not intended to be an all-inclusive list of violations. As an example, you may have other feeds that are not labeled correctly. You are responsible for assuring that the animal feeds you manufacture and distribute are in compliance with the law.

You should take prompt action to correct the above violation and to establish procedures whereby such violations do not occur. You should consider not only those finished products in your inventory, but also those, which you have distributed and may still be available for sale in the market place. Failure to take corrective action may result in regulatory action without further notice, such as seizure of products and/or injunction.

You should notify this office in writing within 15 working days of the receipt of this letter describing the steps you have taken to bring your firm and products into compliance with the law. Your response should include each step taken or will be taken to correct the

violations and prevent their recurrence. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Please send your reply to the Food and Drug Administration, Attention: Richard Andros, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have any questions regarding any issue in this letter, please contact Richard Andros at (425) 483-4980.

Sincerely yours,

/Kristy R. Ellis/
for Austin R. Long, Ph. D.
Acting District Director